4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. FDA-2013-N-0003]

Institutional Review Boards; Correcting Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding institutional review boards to address a minor correction to the regulatory text and to update contact information. This action is editorial in nature and is intended to provide accuracy and clarity to the Agency's regulations.

DATES: This final rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

FDA is amending 21 CFR part 56 to correct a minor error in the Code of Federal Regulations (CFR), and to update obsolete information. A minor spelling error was introduced inadvertently in the CFR when the regulations were first published. Also, contact information in the regulations is obsolete and in need of updating.

Publication of this document constitutes final action under the Administrative Procedures Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to correct minor errors and to update obsolete information, and is nonsubstantive.

List of Subjects in 21 CFR Part 56

Human research subjects, Reporting and reporting requirements, and Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 56 is amended as follows:

PART 56--INSTITUTIONAL REVIEW BOARDS

1. The authority citation for 21 CFR part 56 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b-263n.

2. In § 56.106 revise paragraph (d) to read as follows:

§ 56.106 Registration.

* * * * *

(d) Where can an IRB register? Each IRB may register electronically through http://ohrp.cit.nih.gov/efile. If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to the Office of Good Clinical Practice, Office of Special

Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993.

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3. Section 56.107 is amended in paragraph (a), by revising the 3rd sentence to read as follows:

§ 56.107 IRB membership.

(a) * * * In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * *

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Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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